

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION**

UNITED STATES OF AMERICA

v.

CASE NO. 1:19cr00016

**INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and
INDIVIOR PLC**

**MEMORANDUM IN SUPPORT OF DEFENDANTS’
MOTION TO DISMISS THE SUPERSEDING INDICTMENT, TO STRIKE
SURPLUSAGE AND FOR INSPECTION OF GRAND JURY MATERIALS***

Defendants Indivior Inc. and Indivior PLC (“Defendants” or “Indivior”) respectfully move the Court to dismiss Counts Seven, Eleven, and Thirteen through Twenty-Eight for failure to state an offense. Indivior further moves to strike as surplusage all allegations that Indivior “aided and abetted” physicians who supposedly prescribed buprenorphine-containing drugs in a “careless or clinically unwarranted manner.”

The Superseding Indictment alleges two distinct sets of conduct. First, the Superseding Indictment alleges that Indivior made false representations that Suboxone Film was “safer and less subject to diversion and abuse than other, similar drugs.” Sup. Ind. ¶¶ 1, 16-96 (“Misrepresentation Allegations”). Second, the government alleges that Indivior knowingly connected patients to physicians, exemplified by Doctors A through D, who “were prescribing Suboxone and/or other opioids in a careless and clinically unwarranted manner.” *Id.* ¶¶ 1, 97-143 (“Careless Prescription Allegations”). The two sets of allegations are unconnected except for a purported overarching motive to increase prescriptions and “boost” profits for Suboxone

* This publicly filed version of this memorandum is redacted pursuant to this Court’s Order of April 9, 2019, as amended on May 23, 2019 and August 12, 2019. An un-redacted memorandum has been filed under seal.

Film.¹ *Id.* ¶¶ 1, 144-48. As pled, Doctors A through D could be victims of the Misrepresentation Allegations but beneficiaries of Indivior's alleged aiding and abetting the Careless Prescription Allegations. Nevertheless, the government has incorporated these two unrelated sets of alleged conduct, in their entirety, into a single conspiracy and into every single substantive count.

Counts Seven, Eleven, and Thirteen through Twenty-Eight concern referrals to Doctor A and relate to the Careless Prescriber Allegations. *Id.* at 41-42 (Wire Fraud Counts). While the Superseding Indictment repeatedly alleges that Indivior aided and abetted physicians who prescribed in a "careless and clinically unwarranted manner" by referring patients to these doctors, it never alleges that the physicians were the principal violators of any federal offense, much less sets out clearly the elements of that offense or any factual allegations to support it. Thus, the allegations that Indivior is liable for fraud based on the physicians' unnecessary prescriptions fails to state an offense. In the absence of allegations that the physicians' conduct constituted fraud, it follows that Indivior cannot "aid" or "abet" fraud by connecting patients to those physicians. Thus, those allegations should be stricken and Counts Seven, Eleven, and Thirteen through Twenty-Eight should be dismissed.²

For the same reasons, the allegations that Indivior aided and abetted physicians who prescribed in a "careless and clinically unwarranted manner" and the related Careless Prescriber Allegations should be stricken from the entirety of the Superseding Indictment as prejudicial surplusage. *Id.* ¶¶ 1, 97-143. Furthermore and in the alternative, to the extent the Court does

¹ It should go without saying that a pharmaceutical company's motive to increase prescriptions to secure a profit for shareholders, in and of itself, cannot be a criminal scheme.

² The government incorporated the Misrepresentation Allegations by reference into every count, however, the Superseding Indictment does not connect any of the alleged false statements described in the Misrepresentation Allegations to the patient referrals that are the subject of Counts Seven, Eleven, and Thirteen through Twenty-Eight. The Misrepresentation Allegations cannot, therefore, save those counts.

not strike the “aiding and abetting” allegations, Indivior moves the Court to dismiss Counts One and Two for duplicity because both counts allege two wholly separate conspiracies and schemes in single counts. Finally, Indivior also respectfully moves the Court to order inspection of grand jury materials solely related to the return of the Superseding Indictment to determine whether the prosecution impermissibly usurped the independence of the grand jury in contravention of the Fifth Amendment.

BACKGROUND

Indivior developed Suboxone for the treatment of opioid dependence, which for the first time gave patients the ability to take their medicine at home instead of travelling to a methadone clinic. *Id.* ¶¶ 12-13. In fact, when the FDA approved Indivior’s Suboxone Sublingual Tablet (“Suboxone Tablet”) in 2002, it was the first drug of its kind approved for opioid addiction treatment outside of a clinic. *Id.* The FDA has continued to approve several forms of Indivior’s products, including Suboxone Sublingual Film (“Suboxone Film”) in 2010. *Id.* ¶¶ 13-15, 29.

A. The Superseding Indictment

The Superseding Indictment alleges that Indivior executed a scheme to increase prescriptions of Suboxone Film by deceiving health care providers and others that Suboxone Film is “safer and less susceptible to diversion and abuse than other, similar drugs.” *Id.* ¶ 1. The Superseding Indictment also alleges that Indivior “marketed Suboxone Film to health care providers to be prescribed and dispensed in a careless and clinically unwarranted manner.” *Id.* at 26; *see id.* ¶¶ 97, 102, 113, 128; Count II ¶ 4(d). The first 34 pages of the sprawling 46 pages purport to lay out the factual basis for the Superseding Indictment’s allegations. *Id.* ¶¶ 1, 12-144. For example, the Superseding Indictment alleges that Indivior made “materially false and fraudulent statements and representations to health care providers,” *id.* ¶¶ 32-75, prepared

“materially false and fraudulent marketing materials,” *id.* ¶¶ 76-77, and made “materially false and fraudulent statements and representations to . . . state Medicaid administrators and others” regarding the benefits of prescribing Suboxone Film over other products, including Suboxone Tablets. *Id.* ¶¶ 78-96.

In addition, the Superseding Indictment alleges that Indivior “did aid, abet, counsel, command, induce, and procure physicians . . . who they knew were prescribing buprenorphine-containing drugs to more patients at a time than allowed by federal law (*i.e.*, the DATA), at daily doses higher than 24 mgs of buprenorphine (*i.e.*, in excess of the maximum dose of any demonstrated additional clinical advantage), and in a careless and clinically unwarranted manner, to switch their prescribing to Suboxone film.” *Id.* ¶ 97; *see also id.* ¶¶ 98-143. The Superseding Indictment specifically alleges that Indivior aided and abetted four physicians “it knew were issuing careless, clinically unwarranted opioid prescriptions.” *Id.* ¶¶ 102-12 (Doctor A); *id.* ¶¶ 113-27 (Doctors B & C); *id.* ¶¶ 128-43 (Doctor D). And it alleges that Indivior aided and abetted these doctors by including them in Indivior’s “Here to Help” physician referral program, *id.* ¶ 98, and providing them with “marketing materials, billing advice, and access to lunch and dinner events.” *Id.* ¶ 99.

Notably though, nowhere does the Superseding Indictment allege that these doctors committed health care, wire or mail fraud or any other kind of criminal offense by prescribing in a “careless or clinically unwarranted manner.” Nor does the Superseding Indictment link *any* patient referral to any doctor’s prescribing practices. To the contrary, the Superseding Indictment makes clear that patient referrals were based not on whether a particular doctor switched from Suboxone tablets to film, but rather, on “a list of enrolled prescribers in the patient’s geographic area.” Sup Ind. ¶¶ 106, 108, 110, 112, 117, 125, 127, 132, 137.

The Superseding Indictment then charges Indivior with Twenty-Eight Counts, each incorporating wholesale *all* of the factual allegations laid out in the preceding paragraphs of the Superseding Indictment, while each failing to identify which of the allegations apply to the criminal conduct charged in that specific count. For example, Count One charges that “Indivior PLC, Indivior Inc. . . . and others known and unknown to the Grand Jury knowingly conspired” to commit mail, wire, and health care fraud, and merely lists the elements of each fraud offense. Count One never identifies *who* is in the conspiracy, the *object* of the conspiracy, the *means* used to carry out the conspiracy, or the *overt acts* committed in support of the conspiracy. Sup. Ind. at 36-37; *see also* Mem. in Support of Def.’s Mot. for a Bill of Particulars at 12-15 (Sept. 10, 2019), ECF No. 137 (requesting that the government “disclose the identity of Indivior’s alleged co-conspirators, summarize the agreement or agreements underlying its conspiracy charge, and identify the overt acts supporting the charge.”).

Count Two charges health care fraud, alleging that the object of the scheme was “to fraudulently induce physicians to write prescriptions for Suboxone Film, pharmacists to fill prescriptions for Suboxone Film, and health care benefit programs to provide coverage of prescriptions for Suboxone Film.” Sup. Ind. at 38. The scheme’s supposed goal was to eventually cause “wholesalers, distributors, and others to make payments” to Indivior “for sales of Suboxone Film.” *Id.* In furtherance of this scheme, Count Two alleges generally that Indivior made, and aided and abetted others, in making “materially false and fraudulent statements and representations” to “physicians,” “pharmacists,” and “government officials” about Suboxone Film. *Id.* at 38-39. Count Two also alleges Indivior made, or aided and abetted, false representations by “[p]roviding patient referrals, presentations, . . . and other benefits to physicians they knew were prescribing buprenorphine-containing drugs . . . in a careless and

clinically unwarranted manner.” *Id.* at 39 ¶ 4(d). There are no factual allegations, either in Count Two or in the 148-paragraph Introduction, that Indivior made any fraudulent statements to or about these physicians, nor are there any factual allegations about how connecting patients to duly licensed and certified physicians contributed to unwarranted prescriptions or otherwise constituted fraud.

Counts Three to Six charge mail fraud, premised on sending allegedly false marketing materials to Indivior sales representatives, *id.* at 40-41, and Counts Seven through Twenty-Eight charge wire fraud. *Id.* at 41-42. However, Counts Seven, Eleven, and Thirteen through Twenty-Eight allege only that Indivior made “referrals of prospective patients to Doctor A.” *Id.* Those counts do not allege that any misrepresentations were made in connection with these referrals, that these referrals were somehow fraudulent, or how these referrals aided or abetted any fraud associated with the physicians’ “careless and clinically unwarranted conduct.” *Id.* at 42; *see id.* at 40-42. Per the Superseding Indictment, those referrals were made by “Here to Help operators . . . using lists of enrolled prescribers in the patients’ geographic areas.” Sup. Ind. ¶¶ 106, 108, 110, 112.

B. The Grand Jury

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

On August 14, 2019, after Indivior moved to dismiss this indictment, the government brought the case before the grand jury once again. This time [REDACTED]

[REDACTED]

⁴ Defs' Response to Government's Sur-Reply Regarding Mot. to Dismiss the Indictment for Compound Grand Jury Misconduct, at ¶ 4 (filed under seal Oct. 1, 2019).

⁵ Decl. of James R. Wooley at ¶¶ 3(D)-(F) (sworn to and submitted under seal Sept. 6, 2019).

⁶ Decl. of Tamara Marinkovic Hines ¶ 4 (sworn and submitted under seal Sept. 6, 2019) ("Hines Decl."); United States' Response in Opposition to Mot. to Dismiss the Indictment, Ex. 1 (filed under seal Aug. 20, 2019).

[REDACTED]

[REDACTED]

[REDACTED] That same day, the grand jury issued the Superseding Indictment.

ARGUMENT

I. THE COURT SHOULD DISMISS OR STRIKE FOR FAILURE TO STATE AN OFFENSE ALL ALLEGATIONS THAT INDIVIOR “AIDED AND ABETTED” PHYSICIANS WHO PRESCRIBED IN A “CARELESS AND CLINICALLY UNWARRANTED” MANNER.

The Superseding Indictment repeatedly alleges that Indivior aided and abetted physicians who prescribed in a “careless and clinically unwarranted manner.” Sup. Ind. ¶¶ 97, 102, 113, 128; *id.* at 39 Count II ¶ 4(d); *see generally id.* ¶¶ 1, 31, 97-143. Although the government parrots Section 2’s aiding and abetting language, *compare id.* ¶¶ 97, 102, 113, 128 with 18 U.S.C. § 2(a) (“aids, abets, counsels, commands, induces or procures”), it never alleges that the physicians were the principal violators of any federal offense, much less sets out clearly the elements of that offense or any factual allegations to support it. To the extent that these allegations purport to attach liability to Indivior for fraud or conspiracy to commit fraud based on the physicians’ unnecessary prescriptions, the Superseding Indictment fails to state an offense, and the Court should thus strike these allegations from the Introduction and Counts One and Two and dismiss Counts Seven, Eleven, and Thirteen through Twenty-Eight.

“[A]n indictment is sufficient if it, first, contains the elements of the offense charged and fairly informs a defendant of the charge against which he must defend, and, second, enables him to plead an acquittal or conviction in bar of future prosecutions for the same offense.” *United States v. Brandon*, 298 F.3d 307, 310 (4th Cir. 2002) (internal quotation marks omitted) (quoting

⁷ Hines Decl. ¶ 5.

Hamling v. United States, 418 U.S. 87, 117 (1974)). Ordinarily, an indictment is sufficient if it “alleges an offense in the words of the statute” and “fully, directly, and expressly, without any uncertainty or ambiguity, set[s] forth all elements necessary to constitute the offence.” *Id.* (quoting *United States v. Wicks*, 187 F.3d 426, 427 (4th Cir. 1999), and *Hamling*, 418 U.S. at 117). If the government merely quotes the statute’s language, however, then the indictment must contain a “statement of the essential facts constituting the offense charged.” Fed. R. Crim. Pro. 7(c)(1). The Superseding Indictment does neither as to the “aiding and abetting” allegations.

To properly state an offense for health care fraud, an indictment must allege that a defendant knowingly and willfully executed or attempted to execute a scheme or artifice “(1) to defraud any health care benefit program; or (2) to obtain by means of false or fraudulent pretenses, representations, or promises, any of the [program’s] money . . . in connection with the delivery of or payment for health care benefits, items, or services.” 18 U.S.C. § 1347. Similarly, to properly state an offense for wire fraud, an indictment must allege that a defendant knowingly and willfully used a wire communication to execute “any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises.” 18 U.S.C. § 1343. Both offenses thus require a “scheme” or “artifice to defraud” and intent to defraud. *See Brandon*, 298 F.3d at 311 (citing *United States v. Akers*, 215 F.3d 1089, 1100 (10th Cir. 2002)).

To the extent the Superseding Indictment purports to attach liability to Indivior for “aiding and abetting” physicians’ careless prescriptions, it is fatally flawed for omitting both of these essential elements. First, because the government makes no attempt to define what it means by “careless and clinically unwarranted,” there are simply no allegations in the Superseding Indictment that support the most fundamental element of either a health care or wire

fraud claim: a scheme to defraud or fraudulent misrepresentations. The Superseding Indictment simply fails to allege that the physicians' prescriptions were false, fraudulent, or in some way constituted a scheme to defraud. In the absence of allegations that the physicians' conduct constituted fraud, it follows that Indivior cannot "aid" or "abet" fraud by connecting patients to those physicians.

Second, nowhere does the government allege that the physicians had the specific intent to deceive through their "careless or clinically unwarranted" prescriptions. Careless conduct simply does not rise to the level of fraudulent intent that is needed to constitute fraud. *See, e.g., United States v. McLean*, 715 F.3d 129, 138 (4th Cir. 2013) (health care fraud requires "specific intent to defraud," i.e., proof that defendant "knowingly and willfully executed a scheme to defraud" (internal quotation marks omitted) (quoting *United States v. Harvey*, 532 F.3d 326, 334 (4th Cir.2008))). Indeed, Indivior cannot find any cases even considering a fraud allegation based on "careless and clinically unwarranted" conduct, much less any case permitting criminal liability to attach to an alleged aider and abettor of such conduct. Simply put, the Superseding Indictment omits essential elements necessary to state an offense of fraud based on a scheme to prescribe unwarranted medication, against the unnamed physicians or Indivior.

Third, even assuming that "careless" could equal "fraudulent," the Superseding Indictment fails to allege how *Indivior* "aided and abetted" that fraudulent prescription scheme by the physicians. Aiding and abetting liability only attaches when a defendant knowingly associates himself with the criminal venture and seeks its success through active participation. *See, e.g., United States v. Horton*, 921 F.2d 540, 543 (4th Cir. 1990) (citing *Nye & Nissen v. United States*, 336 U.S. 613, 619 (1949)). The 148-paragraph Introduction to the Superseding Indictment sets out allegations concerning Indivior's knowing misrepresentations of the benefits

of Suboxone film. But it never alleges that Indivior made any “fraudulent pretenses, representations, or promises” *in relation to* the physicians; how Indivior’s marketing of Suboxone Film aided “careless and clinically unwarranted” prescriptions; or any facts that link Indivior’s purported support of the providers to instances of health care or wire fraud based on careless prescriptions. In fact, the Superseding Indictment does not list even a single example of an improper reimbursement claim that was part of a “careless” prescription scheme, much less any allegations of how Indivior assisted in that claim’s falsity. Judge Sargent recognized this glaring absence at the hearing on Indivior’s motion for a bill of particulars, *see* Tr. of Oct. 1, 2019 Hearing at 37 (ECF No. 205) (“I don’t see that there’s any allegations of specific conduct there dealing with the defendants urging doctors to prescribe or dispense in careless o[r] unwarranted manner,”) and concluded that “[t]he government’s case is not that we have this evidence that the defendants were out there advocating that doctors should be handling more patients than they were supposed to be handling or should be prescribing in greater doses than were effective.” *Id.* at 35. Rather, the government argues that Indivior fraudulently induced physicians to switch from prescribing Suboxone Tablets to Film. *Id.* at 36. But there is no allegation that the interactions between Doctor A and Indivior that form the basis of the substantive wire fraud counts in Counts Seven, Eleven, and Thirteen through Twenty-Eight were fraudulent. Sup. Ind. ¶¶ 102- 112. Nor does the Superseding Indictment link any patient referrals to Doctor A’s prescription practices. To the contrary, those referrals were made by “Here to Help operators . . . using lists of enrolled prescribers in the patients’ geographic areas.” Sup. Ind. ¶¶ 106, 108, 110, 112.

Accordingly, the Court should strike the aiding and abetting allegations related to the physicians’ “careless and clinically unwarranted” conduct in the Introduction and Counts One

and Two and dismiss Counts Seven, Eleven, and Thirteen through Twenty-Eight for failure to state an offense based on “aiding and abetting” the physicians’ “careless” conduct. If the aiding and abetting allegations were intended to be a mere colloquial reference to helping physicians increase business, they should at a minimum be struck, as their verbatim recitation and citation of Section 2 connotes much more.⁸

II. IN THE ALTERNATIVE, THE COURT SHOULD DISMISS COUNTS ONE AND TWO BECAUSE THEY ARE IMPERMISSIBLY DUPLICITOUS.

If the Court determines that the Superseding Indictment sufficiently alleges that Indivior aided and abetted physicians prescribing in a “careless and clinically unwarranted manner,” it should nevertheless dismiss Counts One and Two as impermissibly duplicitous and prejudicial to Indivior. Both counts incorporate by reference all of the allegations in the Introduction to the Superseding Indictment, including the allegations that Indivior misrepresented the benefits of Suboxone film and aided and abetted “careless” prescribing. But these allegations set out two, fundamentally different conspiracies and schemes. The first scheme’s object was to fraudulently induce healthcare providers, healthcare benefit programs, and government officials into switching from Suboxone Tablets and generic buprenorphine tablets to Suboxone Film, with the purported goal of maintaining Indivior’s high revenue yields after the entry of generic tablets into the marketplace. *See* Sup. Ind. ¶¶ 16-29, 32-96. The second scheme’s object (to the extent

⁸ At one point in the hearing on the motion for a bill of particulars, the government represented that Indivior “aided and abetted those doctors in switching to Suboxone Film. That’s what the aiding and abetting was.” Tr. at 39. But that only proves the point that, in order for Indivior to be liable for aiding and abetting, the physicians themselves must be principle violators of some offense, which was never sufficiently alleged. To allow the aiding and abetting allegations to remain would permit the government to seek to introduce prejudicial evidence of a separate scheme wholly different than the alleged scheme of misrepresenting the benefits of Suboxone Film, without even alleging that other scheme’s basic elements or proving its existence at trial. *Id.* at 36 (the government stating it “wouldn’t be required to prove” “that the defendants were urging these doctors to prescribe film to more patients” or “to prescribe it in doses higher than was shown to be clinically effective,” but maintaining that “there may be some evidence” introduced at trial about it.).

it is discernable) was for physicians to prescribe and dispense unwarranted prescriptions of “Suboxone and/or other opioids” and switch to Suboxone Film. *Id.* ¶¶ 1, 97-143.

These two conspiracies and schemes involve fundamentally different objects, different means to achieving their goals, different participants, and different time periods and geographic locations. They cannot fairly be considered part of the same agreement or continuous scheme. In fact, Counts One and Two are internally inconsistent in that they treat the physicians as victims of Indivior’s scheme to defraud through misrepresentations about Suboxone Film’s efficacy, while at the same time incorporating allegations that Indivior aided and abetted those same physicians’ careless prescribing. Importantly, the improper combination of the two offenses in Counts One and Two is highly confusing and exposes Indivior to all the prejudice problems that the prohibition on duplicity is intended to prevent.

A. Legal Standard

“[D]uplicity is the joining in a single count of two or more distinct and separate offenses.” *United States v. Burns*, 990 F.2d 1426, 1438 (4th Cir. 1993) (internal quotation marks omitted); *see* Fed. R. Crim. P. 8(a). Such duplicity invites many invidious harms. Foremost of among these problems is the threat to a defendant’s Sixth Amendment right to a unanimous verdict by creating a significant risk that a jury will “not unanimously agree on the offense” yet nevertheless “convict for the improperly fused double count.” *United States v. Robinson*, 855 F.3d 265, 269 (4th Cir. 2017) (internal quotations omitted) (quoting *United States v. Robinson*, 627 F.3d 941, 957 (4th Cir. 2010)). A duplicitous count may also have other “[a]dverse effects on a defendant,” including “improper notice of the charges against him, prejudice in the shaping of evidentiary rulings, in sentencing, in limiting review on appeal, [and] in exposure to double jeopardy.” *United States v. Blandford*, 33 F.3d 685, 699 n.17 (6th Cir. 1994) (quoting *United States v. Duncan*, 850 F.2d 1104, 1108 n. 4 (6th Cir.1988)); *see also* Wayne R. LaFave et al., 5

Crim. Proc. § 19.3(d) (4th ed. 2015) (“[W]here the jury is not able to reach a verdict or renders a guilty verdict that is later overturned, the defendant may be subjected to a second trial that exposes him to double jeopardy insofar as it includes an offense on which the original jury would have acquitted if required to render separate verdicts.” (footnotes omitted)).

For conspiracy allegations, a count is impermissibly duplicitous if it charges more than one conspiracy “when multiple conspiracies exist.” *United States v. Urbanik* 801 F.2d 692, 695 (4th Cir. 1986) (citing *Kotteakos v. United States*, 328 U.S. 750 (1946)); *see also United States v. Witasick*, No. 4:07-CR-00030, 2008 WL 1924023, at *1 (W.D. Va. Apr. 28, 2008) (holding that “the government should have charged the different agreements as individual conspiracies,” and that charging them in one count was impermissibly duplicitous); *United States v. Berlin*, 707 F. Supp. 832, 836 (E.D. Va. 1989) (“There is no doubt that an indictment cannot charge two conspiracies in a single count.”) (citing *Kotteakos*, 328 U.S. 750). A single count of conspiracy is not duplicitous if it charges “one overall agreement,” *United States v. Leavis*, 853 F.2d 215, 218 (4th Cir. 1988) (internal quotation marks omitted), but it *is* impermissibly duplicitous when it alleges independent agreements. *See, e.g., Witasick*, 2008 WL 1924023, at *1. Courts look to the “totality of the circumstances” to determine the number of conspiracies alleged, *United States v. Ragins*, 840 F.2d 1184, 1188-89 (4th Cir. 1988) (internal quotation marks omitted), including “the overlap of key actors, methods, and goals.” *Leavis*, 853 F.2d at 218.

For offenses that involve fraudulent schemes, a count is duplicitous if it charges two or more acts that cannot be characterized “as part of a single, continuing scheme.” *United States v. Burfoot*, 899 F.3d 326, 337 (4th Cir. 2018) (internal quotation marks omitted). “Where the indictment ‘fairly interpreted’ alleges a ‘continuing course of conduct, during a discrete period of time,’ the indictment is not prejudicially duplicitous.” *United States v. Davis*, 471 F.3d 783,

790 (7th Cir. 2006) (citation omitted). As such, the key is whether the multiple acts constitute “a continuous scheme” by a defendant and whether their joinder in a single count produces any of the potential prejudice problems that underlie the doctrine against duplicitous charges. *Burfoot*, 899 F.3d at 337.

B. Count One is Duplicitous Because It Alleges Multiple Conspiracies.

Count One charges two separate conspiracies: one to defraud healthcare providers and benefit programs by allegedly misrepresenting the benefits of Suboxone Film over Suboxone Tablets, and the other to conspire with doctors who prescribe buprenorphine products in a careless and clinically unwarranted manner. Judge Sargent correctly acknowledged that “the alleged fraud didn’t have anything to do with the numbers of ... patients or the dosing,” Tr. Oct. 1, 2019 at 43, but the government has insisted that the allegations regarding physicians who prescribe in a “careless and clinically unwarranted manner” are “part of the conspiracy and that’s part of the fraud.” *Id.* at 39, 42-43, 45. The government is wrong. These two conspiracies do not describe “one overall agreement”—they have different objects and means, involve different participants, and span different geographic and temporal scopes.

Take the objects and means first. With respect to the first conspiracy, the government alleges that Indivior enacted a scheme to “promote Suboxone Film by claiming it was safer than alternative drugs such as tablets” in anticipation of the market entry of generic versions of Suboxone Tablets. Sup. Ind. ¶¶ 16-17. The Superseding Indictment alleges that in order to carry out this scheme, various Indivior employees made representations to physicians and others that Suboxone Film was safer than Suboxone Tablets, *id.* ¶¶ 32-75, 90-96, the company published marketing materials that misrepresented the benefits of Suboxone Film, *id.* ¶¶ 76-77, and the company discontinued the Suboxone Tablet and submitted a Citizens Petition to the FDA falsely

stating that the discontinuance was for safety reasons in order “to delay FDA approval of generic Suboxone.” *Id.* ¶ 84; *see also id.* ¶¶ 78-89.

By contrast, the Superseding Indictment alleges a completely different object and *modus operandi* for the second conspiracy. It alleges that Indivior carried out this scheme by including physicians who it knew prescribed in a careless or clinically unwarranted manner on Indivior’s “Here to Help” referral list, and providing them with benefits such as “marketing materials, billing advice, and access to lunch and dinner events.” *Id.* ¶¶ 98-99. It specifically alleges that Indivior aided and abetted four particular doctors. *Id.* ¶¶ 102-43. Although not a formal clarification, the government has described this conspiracy to commit fraud as when “the company is trying to get a doctor to write a prescription for film and it’s illegitimate.” Tr. Oct. 1, 2019 at 43. A conspiracy to write and dispense illegitimate Suboxone Film prescriptions, whether based on concepts of high-dosing or DATA 2000 patient caps, is *not* the same object or method of a scheme to defraud by inducing physicians and others to switch to Suboxone Film through misrepresentations. *Cf. Leavis*, 853 F.2d at 218 (duplicity is determined based upon the “overlap of key actors, methods, and goals” of the conspiracies).

The two alleged conspiracies also have different participants and contemplate different relationships between Indivior staff and healthcare providers. The Superseding Indictment alleges that physicians are the *victims* of Indivior’s purported misrepresentations regarding the benefits of Suboxone Film, while the physicians are the *co-conspirators* of the illegitimate prescriptions conspiracy. Even if the Superseding Indictment’s allegations about Indivior’s “executives, employees, and agents” refer to the same Indivior actors for both conspiracies (a fact not explicitly alleged), *compare* Sup. Ind. ¶¶ 32, 76, 78, *with id.* ¶¶ 97, 102, 113, 128, that

does not necessarily mean they all entered into “one common plan or scheme.” *United States v. Velasquez*, 772 F.2d 1348, 1353 (7th Cir. 1985).

Finally, the temporal and geographic scopes of the two conspiracies differ. The first conspiracy is alleged to have begun in 2006, when the company began considering the end of the Suboxone Tablets’ exclusivity period. Sup. Ind. ¶¶ 17, 18, 32, 78. The facts alleged in the Superseding Indictment suggest that it continued only until 2013, when Indivior’s managers are alleged to have decided that “[u]nder no circumstances can we make the claim that Suboxone Film is safer or better at reducing pediatric exposures.” *Id.* ¶ 75; *see also id.* ¶ 96 (latest misrepresentation alleged in the Superseding Indictment is from December 2013). By contrast, the factual allegations supporting the second conspiracy span from 2008 to 2016, and focus on the period after Suboxone Film went to market in 2010. *See id.* ¶¶ 97-143. The Superseding Indictment alleges that the first conspiracy involved representations transmitted to parties in many states. *See, e.g., id.* ¶¶ 43-72, 76-77, 91-96. Although it summarily alleges that Indivior aided and abetted the second conspiracy “at various locations throughout the United States,” *id.* ¶ 97, all of the specific factual allegations involve conduct that occurred only in Virginia, Tennessee, or Kentucky. *Id.* ¶¶ 102, 113, 128.

C. Count Two is Duplicitous Because it Alleges Multiple Fraudulent Schemes.

For many of the same reasons, Count Two is likewise impermissibly duplicitous because it sweeps in multiple fraudulent schemes orchestrated by different actors over different spans of time that are not “part of a single, continuing scheme.” *Burfoot*, 899 F.3d at 337 (internal quotation marks omitted). As explained above, the objects, the means, and the participants that the Superseding Indictment alleges were involved in the two schemes demonstrate on its face why they are not part of a “continuous scheme.” *Id.* Perhaps more damning, however, is the government’s own admission that these two schemes do not share a “discrete period of time.”

Davis, 471 F.3d at 790 (internal quotation marks omitted). At the hearing before Judge Sargent, the government clarified its allegations, stating that “the company was doing [the second scheme] before they switched it to film.” Tr. Oct. 1, 2019 at 35 (“When they just had a tablet, they wanted these doctors to write the drugs also.”). Accordingly, the second scheme does not share the necessary timeframe as the first scheme.

D. The Court Should Dismiss Counts One and Two to Remedy the Duplicity.

Counts One and Two pose all the prejudicial problems that the doctrine prohibiting duplicity is designed to prevent. First, both counts are wildly confusing to any jury. As Judge Sargent repeatedly expressed, the aiding and abetting allegations related to the second conspiracy and scheme are “unclear” and cause confusion. *See* Tr. of Oct. 1, 2019 at 33, 36-37, 42-43 (explaining that “this is where my confusion was” and that these allegations “left me a little confused as to what the alleged illegal conduct was” and whether the conspiracy involved only misrepresentations “that [Suboxone Film] was a safer formulation” or also included a conspiracy charge about doctors prescribing to too many patients or in too high doses, and even suggesting that “the government need[s] to be clearer on that particular allegation”). By incorporating all allegations into every count without distinguishing which supports which elements and by using terms of legal significance (“aiding and abetting”), the government has profoundly muddled the charges and has created a substantial risk of jury confusion, thereby endangering Indivior’s constitutional right to a unanimous jury. There is an unacceptable risk that some jurors might believe the prosecution proved the first scheme, while others believe the prosecution proved the latter. Nor is this problem merely theoretical as the government has already proclaimed its right to introduce evidence of the “aiding and abetting” conspiracy as part of the “switch to film” conspiracy. *See id.* at 39-40. Thus, the possibility of a conviction by a jury that is not

unanimous is a very real threat to Indivior, as is the threat of a double jeopardy violation if a jury does not reach a verdict or if a guilty verdict is later overturned.

Second, and related, the duplicitous counts do not provide Indivior with the constitutionally required notice of the charges it will need to defend against at trial. Under the Fifth and Sixth Amendments, a defendant is guaranteed the right to be indicted only by a grand jury and “be informed of the nature and cause of the accusation.” Indeed, that lack of fair notice is the very reason for Indivior’s earlier motion for a bill of particulars. *See, e.g.*, Memo. in Support of Defs’ Motion for A Bill of Particulars at 12-15 (Sept. 10, 2010) (ECF No. 137) (noting that “rather than providing any detail on the overt acts in which Indivior and its co-conspirators are alleged to have engaged, the Indictment simply states that Indivior and its coconspirators committed all the overt acts described in the Introduction and in the other twenty-seven Counts in the Indictment”). Without it, Indivior cannot adequately prepare for trial and will suffer from prejudicial surprise, as the government may morph its scope of the conspiracies and schemes, even if they are not the ones that the grand jury indicted.

Finally, the impermissible combination of separate charges into single counts leaves Indivior vulnerable to prejudicial evidentiary rulings. As noted above, the government has already promised that it will seek to introduce evidence of different actors’ allegedly wrongful conduct. The government should not be allowed to draft duplicitous counts and then backdoor evidence of other crimes under the veil that they are “intrinsic” to the charged offenses.

Given that the duplicity of Counts One and Two pose substantial threats of prejudice and cannot be easily amended by the court, the proper remedy is dismissal. *United States v. Rigas*, 605 F.3d 194, 210 (3d Cir. 2010) (“An impermissibly duplicitous indictment is subject to dismissal.”). In circumstances where allowing the government to elect which charge to pursue

and striking the other charge causes an “amendment of form (deletion of surplusage) [rather than] of substance (altering nature of charge),” providing for such election is also an acceptable remedy for duplicity. *United States v. Aguilar*, 756 F.2d 1418, 1423 (9th Cir. 1985); *see United States v. Pleasant*, 125 F. Supp. 2d 173, 176 (E.D. Va. 2000). But that is not the case here. “[T]o strike the so-called surplusage would require the court to identify the offense which the grand jury intended to charge and delete the rest of the text of the indictment. Thus, the court would in essence rewrite the indictment.” *Pleasant*, 125 F. Supp. 2d at 184; *Aguilar*, 756 F.2d at 1423 (“[C]hoosing one offense within the count to prosecute and treating the rest of that count as surplusage can be challenged as improper amendment of the indictment.”). Because such substantive amendment would impinge on Indivior’s Fifth Amendment right to “have the grand jury make the charge on its own judgment,” dismissal, rather than election, is the appropriate remedy for the duplicity in Counts One and Two. *Stirone v. United States*, 361 U.S. 212, 218-19 (1960); *see also United States v. Lentz*, 524 F.3d 501, 511 (4th Cir. 2008) (“[T]he court cannot permit a defendant to be tried on charges that are not made in the indictment against him.” (internal quotation marks omitted)); *United States v. Randall*, 171 F.3d 195, 203 (4th Cir. 1999) (“[O]nly the grand jury may broaden or alter the charges in the indictment.”).

III. THE COURT SHOULD ORDER DISCLOSURE OF GRAND JURY MATERIALS.

The Fifth Amendment guarantees a defendant the right not to be tried for a felony “unless on a presentment or indictment of a Grand Jury.” U.S. Const. amend. V. “Historically, [the grand jury] has been regarded as a primary security to the innocent against hasty, malicious and oppressive persecution.” *Wood v. Georgia*, 370 U.S. 375, 390 (1962). This Fifth Amendment guarantee, however, “presupposes an investigative body ‘acting independently of either prosecuting attorney or judge.’” *United States v. Dionisio*, 410 U.S. 1, 16 (1973) (quoting

Stirone v. United States, 361 U.S. 212, 218 (1960)); *see also United States v. Acquest Dev., LLC*, 932 F. Supp. 2d 453, 462 (W.D.N.Y. 2013) (dismissing an indictment where the court had “grave doubt” that the grand jury returned the indictment “on its own judgment”). If this Fifth Amendment right has any substance, the grand jury must be allowed to make independent determinations of probable cause without undue pressure from prosecutors. But the grand jury cannot make such independent determinations when prosecutors treat it as a rubber stamp and deprive it of a full opportunity to consider any of the evidence purportedly supporting the charges. *Cf. United States v. Samango*, 607 F.2d 877, 882 (9th Cir. 1979) (“If the grand jury is to accomplish either of its functions, independent determination of probable cause that a crime has been committed and protection of citizens against unfounded prosecutions, limits must be set on the manipulation of grand juries by over-zealous prosecutors.”).

For example, in *United States v. Samango*, the Ninth Circuit affirmed the dismissal of an indictment for bias where, after presenting to a third grand jury live testimony from only one witness—a government agent whose testimony consisted solely of conclusory statements—“the prosecutor left an accumulated 1,000 pages of transcripts and a prepared Superseding Indictment [with the grand jury] . . . and informed them off the record that he had” a deadline in eight days. *Id.* at 879, 882. Noting that the grand jury issued the indictment that same day, the court acknowledged the danger that the grand jury read the transcripts without any context regarding the witnesses’ credibility, “never even read it[,] or . . . read it too quickly.” *Id.* at 883. The court explained that “[n]either by depriving the grand jury of its opportunity to evaluate the credibility of witnesses nor by making prejudicial remarks to sway the grand jury may the prosecutor deny the accused this substantial right’ [to have the grand jury make the charge on its own judgment].” *Id.* at 884 (quoting *United States v. Gallo*, 394 F. Supp. 310, 314 (D. Conn. 1975)).

Similarly, in *United States v. Leeper*, No. 06-cr-58A, 2006 WL 1455485 (W.D.N.Y. May 22, 2006), in dismissing a superseding indictment, the court emphasized the length of the entire grand jury proceeding (approximately one hour) and the amount of time the grand jury was given to review transcripts of testimony presented to a previous grand jury (about 10 minutes) as evidence that the prosecution treated the grand jury as a rubber stamp and did not allow it to make its own independent assessment of probable cause. *Id.* at *3-4.

Similarly, in *United States v. Sigma Int'l, Inc.*, 244 F.3d 841, 870–73 (11th Cir. 2001), *reh'g en banc granted, opinion vacated*, 287 F.3d 1325 (11th Cir. 2002),⁹ the Eleventh Circuit reversed an order denying a motion to dismiss where the prosecutor told the grand jury that a previous grand jury had wanted to indict and “was very ‘unhappy’ it was not given the opportunity to vote,” gave the grand jury less than two days to consider a 21-page indictment, and took up half of that time with unsworn, informal commentary on the evidence. The Court explained:

It is clear, for example, that if a prosecutor simply drew up an “indictment,” had a grand jury foreperson sign it, and then used it to charge the defendant with a criminal offense, we would dismiss the “indictment” out of hand as violative of the Fifth Amendment. This is because the “indictment” would in no sense be the product of a constitutionally required grand jury proceeding. So, too, would we dismiss an indictment that was issued by a “kangaroo grand jury”—one whose deliberations were so overborne by a prosecutor or judge that the indictment was, in effect, the prosecutor’s or judge’s handiwork, and not the result of a considered judgment by an independently functioning grand jury.

Id. at 856.

The record here reflects that nothing about the Superseding Indictment is the result of considered, independent judgment of the grand jury. [REDACTED]

⁹ The Eleventh Circuit vacated the panel opinion when it granted rehearing *en banc*, but the case became moot before *en banc* consideration. Although the panel opinion is not binding, it provides a useful lens for analyzing how usurping the grand jury’s independence deprives a defendant of a meaningful right to be indicted by a grand jury.

[REDACTED]

[REDACTED] In addition, as the government itself admitted, for some of the allegations in the original Indictment, such as those relating to Doctor D “no evidence was introduced to the grand jury at all.” Gov. Opp. 2 n.2; *see also* Arraignment and Motions Hearing, at 30 (Oct. 4, 2019), ECF No. 200 (“[T]o be candid with the Court, I’m not sure that all of the allegations about Dr. D . . . w[ere] presented.”).

[REDACTED]

¹⁰ Hines Decl. ¶ 4.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As in *Samango*, *Leeper*, and *Sigma International*, the prosecution’s roughshod treatment of the grand jury amounts to a usurpation of the grand jury’s constitutional role and a violation of Indivior’s Fifth Amendment rights. And this kind of structural wrong cannot be remedied later, as the Fifth Amendment right is intended to prevent a defendant being dragged through an entire criminal trial on charges not supported by the grand jury’s finding of probable cause. Thus “a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury.” Fed. R. Crim. Pro. 6(e)(3)(E)(ii).

To be clear, Indivior is not asking the Court to evaluate whether the Superseding Indictment is supported by sufficient or competent evidence. Rather, it is asking the Court to enforce the Fifth Amendment’s guarantee that a defendant not be forced to defend a federal criminal trial without a finding of probable cause on those allegations by an independent grand

¹¹ *Id.* ¶¶ 4-5; United States’ Response in Opposition to Motion to Dismiss the Indictment, Exhibit 1.

jury. The case demonstrates how the prosecution has usurped the grand jury's constitutional role—by, among other actions, placing before it [REDACTED]

[REDACTED]

[REDACTED]

To protect the defendants' Fifth Amendment rights, the Court should, at minimum, order inspection of the prosecutors' colloquy with the grand jury on August 14, 2019 during the presentation of the Superseding Indictment to determine what information was actually presented to the grand jury in this case.

CONCLUSION

For the above reasons, Indivior respectfully moves the Court to dismiss Counts Seven, Eleven, and Thirteen through Twenty-Eight for failure to state an offense and to strike the “aiding and abetting” allegations in the Introduction and Counts One and Two. Alternatively, Indivior moves the Court to dismiss Counts One and Two for duplicity. Finally, Indivior respectfully moves the Court to order inspection of the colloquy between prosecutors and the grand jury on August 14, 2019 pursuant to Federal Rule of Criminal Procedure 6(e)(3)(E)(ii).

Dated: December 18, 2019

Respectfully submitted,

INDIVIOR INC. (a/k/a Reckitt Benckiser
Pharmaceuticals Inc.) and INDIVIOR PLC

/s/ James P. Loonam

By Counsel

Thomas J. Bondurant, Jr. (VSB No. 18894)

Gentry Locke

10 Franklin Road SE

Roanoke, Virginia. 24022

(540) 983-9389

bondurant@gentrylocke.com

Jennifer S. DeGraw (VSB No. 89962)

Gentry Locke

10 Franklin Road SE

Roanoke, Virginia. 24022

(540) 983-9445

degrow@gentrylocke.com

James P. Loonam (admitted *pro hac vice*)

Jones Day

250 Vesey Street
New York, New York 10281
(212) 326-3808
jloonam@jonesday.com

Kathryn K. Mizelle (admitted *pro hac vice*)

Jones Day

51 Louisiana Avenue NW
Washington, D.C. 20001
(202) 879-3611
kmizelle@jonesday.com

Dia Rasinariu (admitted *pro hac vice*)

Jones Day

51 Louisiana Avenue NW
Washington, D.C. 20001
(202) 879-4657
drasinariu@jonesday.com

Peter J. Romatowski (admitted *pro hac vice*)

Jones Day

51 Louisiana Avenue NW
Washington, D.C. 20001
(202) 879-7625
pjromatowski@jonesday.com

James R. Wooley (admitted *pro hac vice*)

Jones Day

901 Lakeside Avenue
Cleveland, Ohio 44114
(216) 586-7345
jrwooley@jonesday.com

CERTIFICATE OF SERVICE

I hereby certify that I caused the foregoing to be presented to the Clerk of the Court for filing and uploading to the CM/ECF system, which will send notification of such filing to all counsel of record, on this 18 day of December, 2019.

/s/ James P. Loonam.

Counsel for Defendants